DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2015

Pasture Pharma Pte, Ltd
Mrs. Sarah Hassan
US Med Pharm Supplies, Inc.
38129 Spring Canyon Drive
Murrieta, CA 92563

Re: K141875
Trade/Device Name: Pasture 60S Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: March 24, 2015
Received: April 3, 2015

Dear Ms. Hassan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141875

Device Name
Pasture 60S Surgical Mask

Indications for Use *(Describe)*
Pasture 60S Surgical Mask is a surgical mask that is indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

This summary of 510(K) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92(c)

The assigned 510(k) number is: K141875

Manufacturer:

CHAMPAK ENTERPRISE CO., LTD.
27-1, Jhaiming St., Dasi Township,
Taoyuan County, 335,
Taiwan (R.O.C.)

Official Correspondent:

Lloyd Soong
President & CEO
Pasture Pharma Pte, Ltd
8 Boon Lay Way #04-01
Trade Hub 21, Singapore 609964

US agent and correspondent:

Mrs. Sarah Hassan
US Med Pharm Supplies, Inc
38129 Spring Canyon Drive
Murrieta, CA 92563
Phone: 951-239-1933
Fax: 951-239-1933
E-mail: sarah@usmedpharm.com

Date of Submission:

May 1, 2015

Classification name:

Surgical Apparel

Proprietary Name:

Pasture 60S Surgical Mask

Device Classification and Product Code

Classification Name: Surgical Mask (21 CFR §878.4040)

Class: Class II

Classification panel: General and Plastic Surgery

Product Code: FXX

Common name:

Surgical Mask

Regulatory Reference:

21 CFR 878.4040

Predicate Device:

TIDI PRODUCTS, LLC

TIDI® Facemasks

K092580

Labels/ Labeling:

Pasture 60S Surgical Mask will be marketed as single use disposable surgical mask for the Intended Use purpose below.

Intended Use:

Pasture 60S Surgical Mask is a surgical mask that is indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material

Device Description:

Pasture 60S Surgical Mask is a flat pleated surgical mask. It is in 4 layers and composed of PP and Meltblown, also with elastic loops and nosepiece which is the combination of zinc wires and embedded polyester inside of layers.

Comparison to Predicated Devices:

The subject device is substantially equivalent to TIDI® Facemasks cleared under K092580.

Description	**Predicate K092580 TIDI® Facemasks**	**Pasture 60S Surgical Mask**
Outer layer	Polypropylene	Polypropylene
Filter Media	Melt-blown	Meltblown
Inner layer	Polypropylene	Polypropylene
Nose Piece	Aluminum	Combination of zinc wires and embedded polyester
Ear Attachment	Elastic	Synthetic elastic
Mask style	Flat Pleated	Flat Pleated
Design features	3 layers of non-woven fiber with filter web in the middle	4 layers of non-woven fiber containing a filter web

Test	K092580	Pasture 60S Surgical Mask
Fluid Resistance Performance (mmHg)	Pass@80mmHg	Pass@120mmHg
Particulate Filtration Efficiency Performance (%)	99.6	99.4
Bacterial Filtration Efficiency	＞99.9	99.76

Performance (%)		
Differential Pressure (Delta-P) (mmH_2O/cm^2)	3.4	3.33
Flammability Class 1	Class 1	Class 1
Sterile	Non-sterile Single use	Non-sterile Single use
Size	7.0 x 3.5 inches	184±1 x 144±1mm
Indication for Use	Surgical mask are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating personnel from transfer of micro-organisms, body fluids and particulate material.	Pasture 60S Surgical Mask is a surgical mask indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.
Biocompatibility Test	Not available	Cytotoxicity: non-cytotoxic
	Not available	Sensitization: non-sensitizing
	Not available	Primary skin irritation: non-irritating

Performance Tests:

Test Performed	**Laboratory**
1. Biocompatibility test :	SUPER LABORATORY SGS (TAIWAN) LTD
2. Flammability test :	Taiwan Textile Research Institute
3. Synthetic Blood Penetration test :	Taiwan Textile Research Institute
4. Particulate Filtration Efficiency :	Nelson Laboratories
5. Bacterial filtration efficiency:	Taiwan Textile Research Institute
6. Differential pressure testing:	Taiwan Textile Research Institute

Conclusions:

The test data submitted in this submission demonstrate that the subject device is as safe and as effective as the predicate and technological characteristics do not raise any new questions of safety and as effectiveness. Pasture 60S Surgical Mask is substantially equivalent to the predicate cleared in K092580.